DEPARTMENT OF HEALTH AND HUMAN SERVICES

93035A

Food and Drug Administration
New Orleans District
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

January 18, 2002

VIA FEDERAL EXPRESS

J. Randall Mayes, Owner
216 Quail Wood Dr.
Pulaski, TN 38478

WARNING LETTER – 02-NSV-10

Dear Mr. Mayes:

An inspection at your diary farm located in Pulaski, TN was conducted by our investigator on November 26 - 28, 2001. That inspection confirmed that you offered a cow for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused an animal drug to become adulterated within the meaning of Section 501(a)(5). You can find this Act and associated regulations through links on FDA's homepage at www.fda.gov.

On or about October 24, 2001, you sold a cow, identified by U.S. Department of Agriculture (USDA) sample number 407433 and back tag number 63IW 7890, for slaughter as human food at [redacted], through [redacted]. USDA analysis of tissue samples collected from that cow identified the presence of 7.12 parts per million (PPM) of gentamicin in the kidney tissue. There is no established tolerance for gentamicin in cattle (Title 21, Code of Federal Regulations (21 CFR), 556.300). The presence of this drug in the edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions, which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You are adulterating the drug, Vedco GentaVed Injection containing gentamicin sulfate within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Gentamicin is not approved for use in dairy cattle. Use of this drug contrary to the approved conditions of use may only be done when a veterinarian is involved in the decision based on a valid veterinarian/client/patient relationship, no residue occurs, and other conditions described in 21 CFR, Part 530, Extralabel Drug Use in Animals, have been met.

This letter may not list all the deviations at your firm. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of the steps that you have taken to bring your farm into compliance with the law. Your response should include each step taken to correct the violations and prevent their recurrence. If you cannot complete all corrections within 15 working days, we expect you to explain the reason for your delay and state when any remaining deviations will be corrected. Please include copies of any documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

KGS:man

cc: w/copy 483:
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